But he said he believed it "is reasonable to assume that the novobiocin component increases the risks of adverse reaction."

Dr. Ley added the FDA, in reaching its decision, also took into account blood level studies in which the novobiocin and tetracycline levels were assayed and the opinions of "experts in anti-infective medicine, across the country, who have expressed themselves in journal articles and editorials for the past few years, in opposition to the use of fixed combination drugs such as Panalba."

In the instance of blood level studies, Dr. Ley said it was determined that novobiocin in Panalba "does nothing to improve the action of tetracycline against organisms susceptible to it."

And in obtaining "expert opinion," one of those taken into account was Harry F. Dowling, MD, former chairman of the AMA's Council on Drugs. Dr. Ley quoted part of a 1967 statement by Dr. Dowling which declared:

"In one area there is complete agreement among clinicians working with infectious diseases; there is no need to market fixed combinations of antibiotics."

Mr. HARRISON. There is a statement that was issued about this time, just a short page or a page and a half. I will read it quickly and at least will describe the background with respect to this change. I can read it better than I might do it off the cuff.

For 79 years, from the launching of the Journal of the American Medical Association in 1883 till 1962, no other means existed in the United States for judging the qualifications of drug advertising, so the AMA established and applied its own standards. For most of this period, there were few prescription drugs and the number of new drugs introduced each year was small.

With the great increase in both the number and complexity of drugs in recent years, Congress in 1962 voted the power to the Food and Drug Administration to set and enforce standards for all drug advertising.

The industry must now conform to these FDA regulations, which have the force of law.

The AMA has continued in the interim period since 1962 to apply its regulations on advertising, while recognizing that the evolving FDA standards were the ones with the power of enforcement behind them. The transition is now far along. In recent years the FDA has been actively enforcing its regulations. It has a current annual budget of $67,296,000, which is more than double the entire budget of the AMA.

At this time, the AMA has neither the resources nor the authority to duplicate or supersede the regulations of the FDA. Its long-time regulations, being somewhat different and not having the force of law, have sometimes caused confusion among manufacturers. Although the AMA has followed the FDA requirements as the primary basis for judging the validity of ads, many physicians and legislators have believed that the existence of separate AMA standards meant the AMA has specifically authenticated every product, every claim, and every other aspect of each advertisement. This is clearly not possible under present conditions.

Accordingly, the AMA will now recognize that the FDA regulations are the basic, enforceable requirements on all technical and scientific aspects, augmented by its own right to refuse any ad it judges to be unethical or in bad taste in a manner not covered by the FDA regulations.

The AMA will also receive FDA rulings regarding any advertisement and transmit appropriate information about these rulings to the entire medical profession in the United States.